

REMARKS

The status of the claims is as follows:

Original: 6, 10, 12-15, 25, 26, 30 and 32

Currently amended: 1, 4, 7-9, and 11

Previously presented: 3, 5, 21-24, 27, 31 and 37

Canceled: 2

Withdrawn: 16-20, 28, 29 and 33-36

Claims 1 and 3-37 are pending, of which claims 1, 3-15, 21-27, 30-32 and 37 are under active consideration.

The particulars of the claim amendments are described below in the remarks directed to the rejections under 35 U.S.C. § 112.

Information Disclosure Statements

Attached hereto as Exhibits A and B are copies of the information disclosure statements filed February 18, 2004 and March 18, 2004 respectively, along with copies of the Express Mail receipts and the post cards showing receipt by the Patent Office. The Examiner is asked to consider these statements, make them of record, and return initialed copies of the 1449 forms with the next communication to Applicants. If the statements and/or the documents cited therein are not in the file, the Examiner is asked to contact the undersigned for replacement copies.

First Rejection under 35 U.S.C. § 112, first paragraph

Claims 25-27 and 30-32 have been rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the description. This rejection is traversed.

The Examiner has questioned whether the mode of action of the naphthyridine compounds is inhibition of the integrase enzyme and indicated that the use of the naphthyridine compounds for treating HIV infection and AIDS is a general idea that may or may not be workable. None of the rejected claims is directed to the inhibition of HIV integrase, so the mode of action of the claimed compounds is not pertinent. The question is whether or not the claimed compounds are useful for treating HIV infection and AIDS. As set forth in the remarks accompanying the amendment filed January 9, 2004, the specification discloses that representative compounds of the invention inhibit HIV replication and describes how to use the compounds of the invention by providing a detailed description of suitable forms, pharmaceutical compositions and their preparation, routes of administration, and dosages. Using this description, optionally in combination with knowhow available in the art, the person of ordinary skill can without undue experimentation prepare and administer a compound of the invention in a suitable carrier and in the appropriate dosage form and dosage amount to a subject in order to

treat HIV infection and AIDS. This is not the "mere germ of an idea" (quoting page 3, line 13 of the Office Action), but is instead an enabling disclosure.

Although no further evidence of enablement beyond that already present in the specification is believed necessary, reference is made to the accompanying Declaration under 37 CFR § 1.132 by Dr. Daria Hazuda. The Declaration presents compelling evidence that the claimed naphthyridine compounds are (i) *in vitro* and *in vivo* inhibitors of HIV replication whose mode of action is inhibition of integrase and (ii) useful for inhibiting integrase, treating HIV infection, delaying the onset of AIDS, and treating AIDS in subjects in need thereof.

In view of the foregoing remarks, withdrawal of the section 112 enablement rejection is requested.

Second Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 3-15, 25-27 and 32 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner has asserted that the definition of the substituent N(R<sup>a</sup>)R<sup>t</sup> for R<sup>k</sup> constitutes new matter when R<sup>a</sup> is hydrogen or C<sub>1-6</sub> haloalkyl. This rejection is traversed with respect to the claims as amended herein.

Claim 1 has been amended to replace "-N(R<sup>a</sup>)R<sup>t</sup>" in the definition of R<sup>k</sup> with "-N(H)R<sup>t</sup> or -N(C<sub>1-6</sub> alkyl)R<sup>t</sup>". Claim 1 as originally filed provides express support for -N(C<sub>1-6</sub> alkyl)R<sup>t</sup>. Support for -N(H)R<sup>t</sup> can be found, for example, in claim 4 as originally filed, which recites -N(R<sup>a</sup>)R<sup>t</sup> (where R<sup>a</sup> is H or C<sub>1-4</sub> alkyl) as a substituent on R<sup>k</sup>. This description reasonably conveys to one skilled in the art that the inventors had possession of the invention as claimed at the time the application was filed.

Claims 4, 7-9 and 11 have been amended to conform with the amendment to claim 1 described in the preceding paragraph.

A minor change in punctuation (i.e., replacement of a comma with a semi-colon) was also made in claim 1, and an extraneous "or" was removed from each of claims 1 and 4.

The claims as amended do not contain new matter.

Withdrawal of the section 112 written description rejection is requested.

Provisional Obviousness-type Double Patenting Rejections

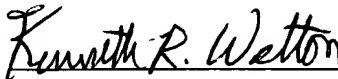
Claims 1, 3-15, 21-27, 30-32 and 37 have been provisionally rejected for obviousness-type double patenting over claims in each of the following copending applications:

A) U.S. Application No. 10/399,083 (Attorney Docket No. 20758YP).

- B) U.S. Application No. 10/486,535 (Attorney Docket No. 20950Y).
- C) U.S. Application No. 10/398,929 (Attorney Docket No. 20760YP).
- D) U.S. Application No. 10/218,537 (Attorney Docket No. 20951Y).

In view of the earlier-described amendments to the claims and the remarks on the section 112 rejections, it is believed that the application is in condition for allowance apart from the provisional double patenting rejections A to D. In accordance with paragraph I.B of MPEP § 804, it is requested that the provisional rejections be withdrawn in this application and that the application be permitted to issue. The Examiner is asked to telephone the undersigned should any minor matters need to be resolved before a Notice of Allowance can be mailed.

Respectfully submitted,

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